EXHIBIT H

U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration

Medical Devices

Questions and Answers About the Baxter Colleague Recall, Refund, and Replacement Action

Updated May 7, 2010

What should hospitals and other Colleague pump users do now?

At this time, clinicians and home-care users may continue to use Colleague pumps during the transition period. The FDA is working with Baxter Healthcare Corp. to develop an orderly transition plan to minimize disruption to health care facilities and patients. The FDA is engaging health care facilities and other stakeholders for their input on this transition plan.

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What should health care providers and other users, such as home care users, of Baxter's Colleague pumps do to mitigate risks associated with the pumps?

The FDA has developed overall strategies for health care professionals and others that use infusion pumps. For general risk reduction strategies for users of infusion pumps see http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/ucm202498.htm[1]. Some of the recommended actions health care providers should consider while the transition plan is in development include:

Have a back-up plan in case the Baxter Colleague infusion pump fails that details:

- How to obtain a working infusion pump and infusion tubing quickly when caring for high-acuity patients.
- How to handle high-risk infusions when the infusion pump fails. This may include staying with and closely monitoring the patient while another staff member obtains a working infusion pump if one is not readily available.
- How to handle infusions when the infusion pump fails in vulnerable patient populations (e.g., individuals sensitive to fluid overload). This may include clamping and disconnecting the infusion tubing from the patient to prevent over-infusion prior to obtaining a new infusion pump.

Notify all your clinicians about this recall and provide information and/or training regarding the issue. For information on problems with the Colleague pumps and actions to address these problems, see the Baxter

Colleague Safety Information page[2].[3]

The FDA believes that Baxter will provide health care facilities and clinicians with information on all known issues associated with Colleague pumps so that health care facilities and clinicians can mitigate the risk to patients while using a Colleague pump until they receive a replacement pump.

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What does this action entail?

The FDA sent a letter to Baxter on April 30, 2010, ordering the company to recall and destroy **ALL MODELS** of its Colleague Volumetric Infusion Pumps (Colleague pumps) currently in use in the United States. The FDA believes there may be as many as 200,000 of the pumps currently in use.

Additionally, the FDA is ordering Baxter to provide refunds to Colleague pump owners or to replace pumps at no cost to pump owners.

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How and when will the Recall, Refund, and Replacement Action occur?

The FDA has ordered Baxter to take the following steps in a letter dated April 30, 2010.

- Recall Colleague infusion pumps
- Provide a:
  - Cash refund or replacement
  - Penalty free termination of Colleague leases
- Provide a transition plan, including its timeline, for transitioning Colleague pump users to alternate pumps.

Baxter is required to respond to the FDA within 15 days.

The FDA and Baxter are working together to develop an orderly transition plan. Once Baxter and the FDA have developed a transition plan, Baxter will provide additional information on their website.

Please note that the information presented here is preliminary and is subject to change.

The FDA is seeking input from those that will be affected by this transition plan. Please submit your input using the feedback form at the bottom of the page. We will update this information based on new information and feedback.

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Why is the FDA requiring Baxter to take this Recall, Refund, and Replacement Action now?

As proposed by Baxter, corrections of longstanding problems with its Colleague pumps would not be complete until 2013. The FDA believes this to be an unacceptable timeframe for these critical care devices. The agency also believes that this timeframe presents an unreasonable risk to public health. The number of recalls and increasing number of adverse events resulting in injuries associated with the Colleague pump has led the agency to take this action.

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Why has the FDA taken so long to address Colleague pumps?

The FDA has worked actively since 1999 to identify and correct problems with the Colleague pump, while being mindful of concerns about the medical necessity of infusion pumps, availability of replacement units, and the financial burden to user facilities of obtaining replacement units.

The FDA has taken a number of actions regarding Colleague pumps, including:

- The seizure of Colleague pumps in October 2005, due to numerous deficiencies identified with Baxter's compliance with the quality system regulation and, numerous defects in the Colleague infusion pumps.
- A June 2006 consent decree, which required Baxter to bring its operations and the distributed Colleague pumps into compliance.
- Seven Class I recalls from 2005 through 2009, for problems including software and hardware defects and battery failures.
- Numerous meetings between the FDA and Baxter.

- Additionally, as required by the consent decree, Baxter has not sold Colleague pumps in the United States since 2006.

In the course of these actions, the FDA has worked continuously with Baxter to communicate both the risks to patients using this pump and the corrections implemented in an attempt to resolve these problems.

The FDA has previously considered removing these pumps from use, but determined that there would be a severe medical device shortage, especially during flu seasons.

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How many Colleague pumps are on the market?

The FDA believes there may be as many as 200,000 Baxter Colleague pumps currently in use. This includes approximately 50,000 triple channel pumps and 150,000 single channel pumps.

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Has the FDA ever ordered a manufacturer to reimburse a recalled device?

This is the first time the FDA has ordered a device company to pay a refund to customers.

The FDA conducted a survey of user facilities and determined that funding for purchasing new pumps was the largest barrier to transitioning to an alternative pump. Therefore, the agency is requiring Baxter to refund or replace the Colleague pumps of customers who own them. For those that lease the pumps, they will not be penalized for terminating the lease agreement and will be refunded the unused portion of the lease.

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What are the possible alternatives?

The FDA has requested the following options from Baxter:

- Cash refund.
- Penalty free termination of Colleague leases.
- Baxter will provide a replacement pump with no charge to the customer.

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Is there an alternative device ready as a replacement?

There are many legally marketed infusion pumps that are currently available for sale in the U.S. Baxter will be providing information on alternative pumps at a later date.

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What about other infusion pumps? Are patients at risk?

Overall, the benefits of infusion pumps outweigh their risks:

- Infusion pumps have contributed to improvements in patient care, allowing for a greater level of control, accuracy, and precision in drug delivery, thereby reducing medication errors
- The alternative, manual infusion or gravity drip also has its own risks and benefits.
- In most situations, using an infusion pump is viewed as the standard of care and the safest route of delivering fluid into a patient's body in a controlled manner.
- To address safety concerns with infusion pumps generally the FDA recently announced an initiative to improve the safety and effectiveness of infusion pumps, which can be found at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/default.htm[4].

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We encourage your feedback on this information and would welcome your suggestions for additional information you would like to see.

Feedback Form

Did you find this information useful?

What other questions would you like to have FDA answer in this section?

Submit Feedback

Links on this page:

1. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/ucm202498.htm
2. http://www.baxter.com/information/safety_information/colleague.html
3. http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm
4. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/default.htm